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I HEREBY CERTIFY that annexed hereto is a true copy of
documents filed in connection with the following patent
application:

Application No. S940613

Date of filing 5 August, 1994

Applicants GAYA LIMITED, a Company organised under
the laws of the Republic of Ireland of
43 Fitzwilliam Place, Dublin 2,
Republic of Ireland.

Dated this 28th day of February, 1995

V. Manning

An officer authorised by the
Controller of Patents, Designs and Trade Marks.

Request for the Grant of a Patent

PATENTS ACT, 1992

The Applicant(s) named herein hereby request(s)

the grant of a patent under Part II of the Act
 the grant of a short-term patent under Part III of the Act

on the basis of the information furnished hereunder

1. Applicant(s)

Name GAYA LIMITED

Address 43, Fitzwilliam Place, Dublin 2, Republic of Ireland.

Description/Nationality A company organised under the laws of the Republic of Ireland.

2. Title of Invention ACCESS DEVICE

3. Declaration of Priority on basis of previously filed application(s) for same invention (Sections 25 & 26)

Previous filing date

Country in or for which filed

Filing No.

4. Identification of Inventor(s)

Name(s) of person(s) believed by Applicant(s) to be the inventor(s)

Address

5. Statement of right to be granted a patent (Section 17(2) (b))

6. Items accompanying this Request - tick as appropriate

- (i) prescribed filing fee (£ 55.00)
- (ii) specification containing a description and claims
 - specification containing a description only
 - drawings referred to in description or claims
- (iii) An abstract
- (iv) Copy of previous application(s) whose priority is claimed
- (v) Translation of previous application whose priority is claimed
- (vi) Authorisation of Agent (this may be given at 8 below if this Request is signed by the Applicant(s))

7. Divisional Application(s)

The following information is applicable to the present application which is made under Section 24 -

Earlier Application No.: Filing Date:

8. Agent

The following is authorised to act as agent in all proceedings connected with the obtaining of a patent to which this request relates and in relation to any patent granted -

MACLACHLAN & DONALDSON, 47 Merrion Square, Dublin 2

9. Address for Service (if different from that at 8)

MACLACHLAN & DONALDSON, at their address as recorded for the time being in the Register of Patent Agents (Rule 92)

Signed Name(s): .. GAYA LIMITED

By: *Dennis Mc Letty*

MACLACHLAN & DONALDSON, Applicants Agents

Capacity (if applicant is a body corporate):

Date August 5 1994

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S940613
APPLICATION No.....

- 1 -

ACCESS DEVICE

The present invention relates to an access port for use in minimally invasive surgery.

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A problem associated with the use of sleeves of the kind described in co-pending patent application entitled "apparatus for use in surgery", is that a phenomenon known as "tenting" occurs. "Tenting" means that when a sleeve 10 is adhered to the patient's skin or to the sterilised wrapping material which in turn is adhered to the patient, then the sleeve has a tendency to pull away from the patient and "lift" the skin upwardly from the patient's abdomen which is inflated using gas for surgery.

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The present invention provides an access device for use in surgery comprising a sleeve having an entry opening located at a proximal end of the sleeve and an exit opening located at a distal end thereof for insertion into an incision made 20 in a patient's body, the exit opening allowing access to the patient's body cavity, and entry sealing means for sealing the entry opening, whereby when the patient's body cavity is inflated by gas, the entry sealing means prevents substantial leakage of gas from the patient's body cavity 25 while providing access for digits of a hand and/or hand itself.

Advantageously, the entry sealing means comprises an inflatable chamber arranged in surrounding relation to the 30 sleeve and capable of exerting a pressure on the sleeve causing at least a portion of it to collapse thereby sealing the entry opening.

Conveniently, the inflatable chamber is not in fluid 35 communication with the patient's body cavity so that the

pressure inside the inflatable chamber may be different from the pressure inside the patient's body cavity.

Preferably, the inflatable chamber is of generally 5 "hour-glass" profile defining an upper chamber and a lower chamber, the lower chamber being insertable into the incision made in the patient's body cavity.

Alternatively, the outer wall of the upper chamber is 10 attached to the inner wall at two diametrically opposed locations.

The present invention will now be described more particularly with reference to the accompanying drawings 15 which shown by way of example only, two embodiments of the invention.

In the drawings:

20 Figure 1 is a perspective view of the access device of the present invention;

Figure 2 is a perspective cut-away sectional view of the access device;

25 Figure 3 is another perspective cut-away sectional view of the access device;

Figure 4 is another perspective view of the access device;

30 Figure 5 is a cross-sectional view of an alternative embodiment of the device; and

Figure 6 is a cross-sectional view of the alternative 35 embodiment at right angles to the cross-sectional view of

Figure 5..

The access device of the invention is indicated generally by the reference numeral 1 and comprises an inflatable chamber having an upper portion 2 and a lower portion 3 which are in fluid communication with each other and having an inlet pipe 4 for supplying gas to inflate both the upper portion 2 and lower portion 3 of the inflatable chamber. A separate pipe is used to inflate the patient's abdominal cavity. The device 1 also includes an adhesive flange 5 which can be adhered to the patient's skin or to the wrapping material, if use. The upper portion 2 of the chamber includes a lip 6 defining an entry opening 7 at the proximal end 8 of sleeve 11, leading to an exit opening 9 at the distal end 10 of the sleeve 11. The device 1 therefore has the advantage that the pressure in the inflated chamber can be controlled independently from the pressure in the patient's abdominal cavity and therefore there can be a pressure differential between the pressure in the cavity and the pressure in the chamber of the access device 1.

In order to use the device 1, the surgeon pushes his gloved hand through the entry opening 7 of the device 1 and down through the sleeve 11. For surgery, an incision is made in the body of the patient, such an incision preferably, being made along the muscle rather than across the muscle of the patient. The distal end 10 of the sleeve 11 together with the lower portion 3 of the inflatable chamber are inserted into the body cavity of the patient (which is not yet inflated, at this stage until the flange 5 contacts the patient's skin or to the wrapping securing means so as to securely hold the access device 1 in place on the patient's body.

To use the device 1, gas is pumped into the inflatable, chamber via pipe 4 until both the upper portion 2 and the lower portion 3 are fully inflated. The action of the muscle tissue around the incision causes the muscle tissue 5 to press against the indented zone 12 defined between the now inflated portion 2 and inflated lower portion 3 of the chamber.

10 The patient's body cavity is then inflated. Since fluid communication is not possible between the patient's body cavity and the inflated chamber of device 1, the pressure within the inflated chamber 6 is not necessarily the same as the pressure within the patient's body cavity.

15 The pressure in the chamber exerts an inward pressure on the sleeve and as shown in Figure 3 the sleeve 11 along the area indicated by the letter A. Similarly, the portion of the sleeve 11 which is in use, located within the inflated abdominal cavity of the patient is also subjected 20 to an inwardly-directed pressure due to the pressure existing in the patient's abdominal cavity and that portion of the sleeve also collapses as indicated by reference numeral B on Figures 3 and 4.

25 The areas A and B respectively act as seals which bear against the upper arm and lower arm respectively, of a surgeon, when the surgeon's hand is inserted through the sleeve and into the patient's abdominal cavity.

30 With reference to the alternative embodiment shown in Figures 5 and 6, the access port consists, nominally, of an outer sleeve A and an inner sleeve B. The applied pressure has the effect of inflating the outer sleeve whilst collapsing the inner sleeve causing the inner sleeve to 35 form a seal in the access passage to the abdominal cavity.

This additional feature is intended to enhance the effectiveness of the seal, especially when the surgeon's arm has been removed from the sleeve.

- 5 The outer sleeve A is attached to the inner sleeve B at two diametrically opposed locations C. This has the effect of locally constraining the outer sleeve effectively causing two "dimples" to form in the outer sleeve. The resulting force F acts on the inner sleeve causing the two walls of
- 10 the inner sleeve to be held in contact. (This is similar in effect to inflating a balloon and stretching the neck of the balloon laterally instead of tying it off). Consequentially, the pressure of the gas in the abdominal cavity is required to overcome the pressure causing the
- 15 inner sleeve to collapse plus the closing effect of the Force F in order for leakage to occur.

It will of course be understood that the invention is not limited to the specific details described herein, which are
20 given by way of example only, and that various modifications and alterations are possible within the scope of the appended claims.

CLAIMS:

1. An access device for use in surgery comprising a sleeve having an entry opening located at a proximal end of the sleeve and an exit opening located at a distal end thereof for insertion into an incision made in a patient's body, the exit opening allowing access to the patient's body cavity, and entry sealing means for sealing the entry opening, whereby when the patient's body cavity is inflated by gas, the entry sealing means prevents substantial leakage of gas from the patient's body cavity while providing access for digits of a hand and/or hand itself.
2. An access device as claimed in claim 1, wherein the entry sealing means comprises an inflatable chamber arranged in surrounding relation to the sleeve and capable of exerting a pressure on the sleeve causing at least a portion of it to collapse thereby sealing the entry opening.
3. An access device as claimed in claim 1 wherein the inflatable chamber is not in fluid communication with the patient's body cavity so that the pressure inside the inflatable chamber may be different from the pressure inside the patient's body cavity.
4. An access device according to any one of the preceding claims wherein the inflatable chamber is of generally "hour-glass" profile defining an upper chamber and a lower chamber, the lower chamber being insertable into the incision made in the patient's body cavity.

5. An access device substantially as herein described with reference to and as shown in the accompanying drawings.

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A B S T R A C T

ACCESS DEVICE

- 5 An access device for use in surgery comprising a sleeve having an entry opening located at a proximal end of the sleeve and an exit opening located at a distal end thereof for insertion into an incision made in a patient's body, the exit opening allowing access to the patient's body
- 10 cavity, and entry sealing means for sealing the entry opening, whereby when the patient's body cavity is inflated by gas, the entry sealing means prevents substantial leakage of gas from the patient's body cavity while providing access for digits of a hand and/or hand itself.
- 15 Fluid communication between the cavity of the patient and the chamber of the access device is not possible.

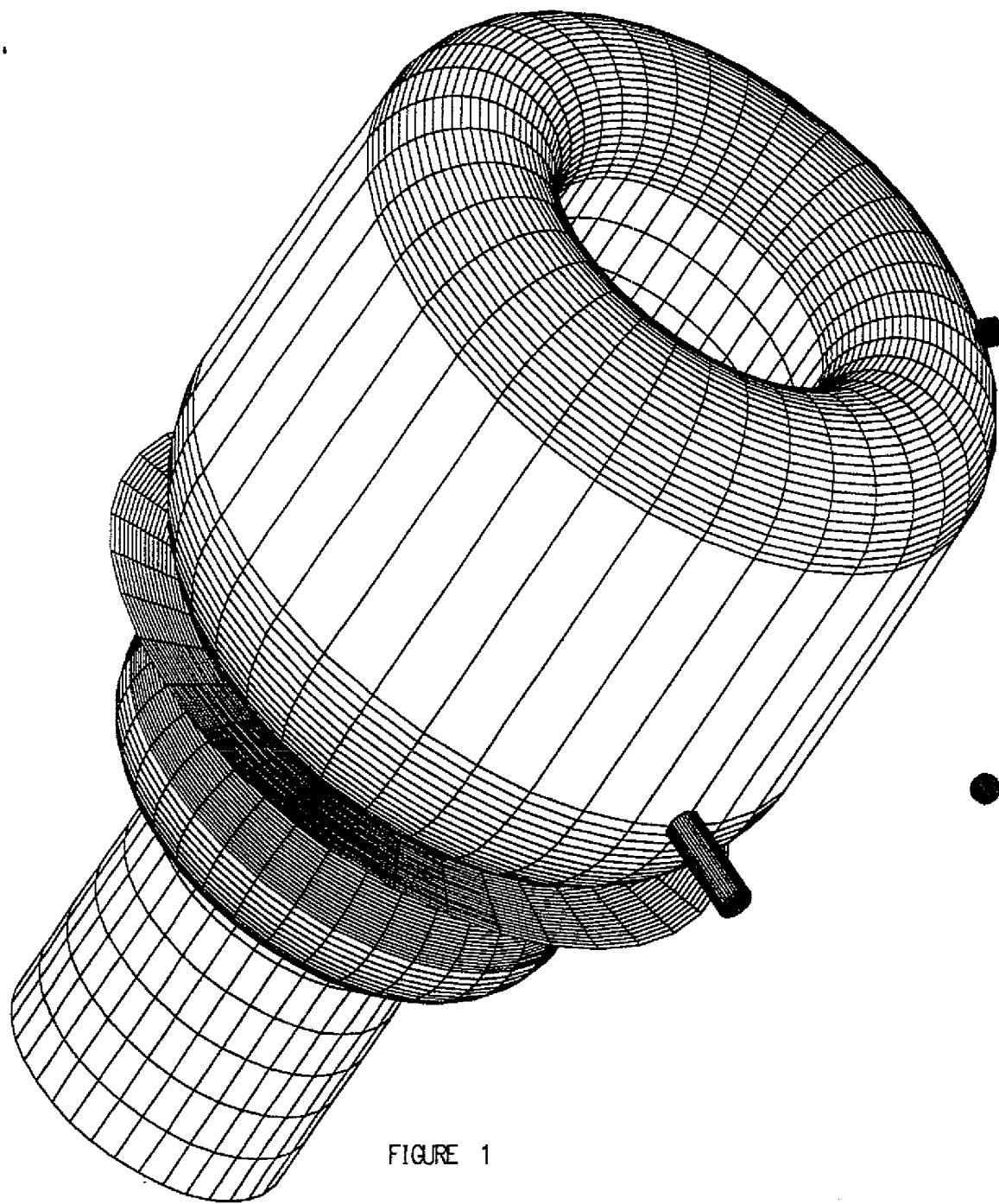


FIGURE 1

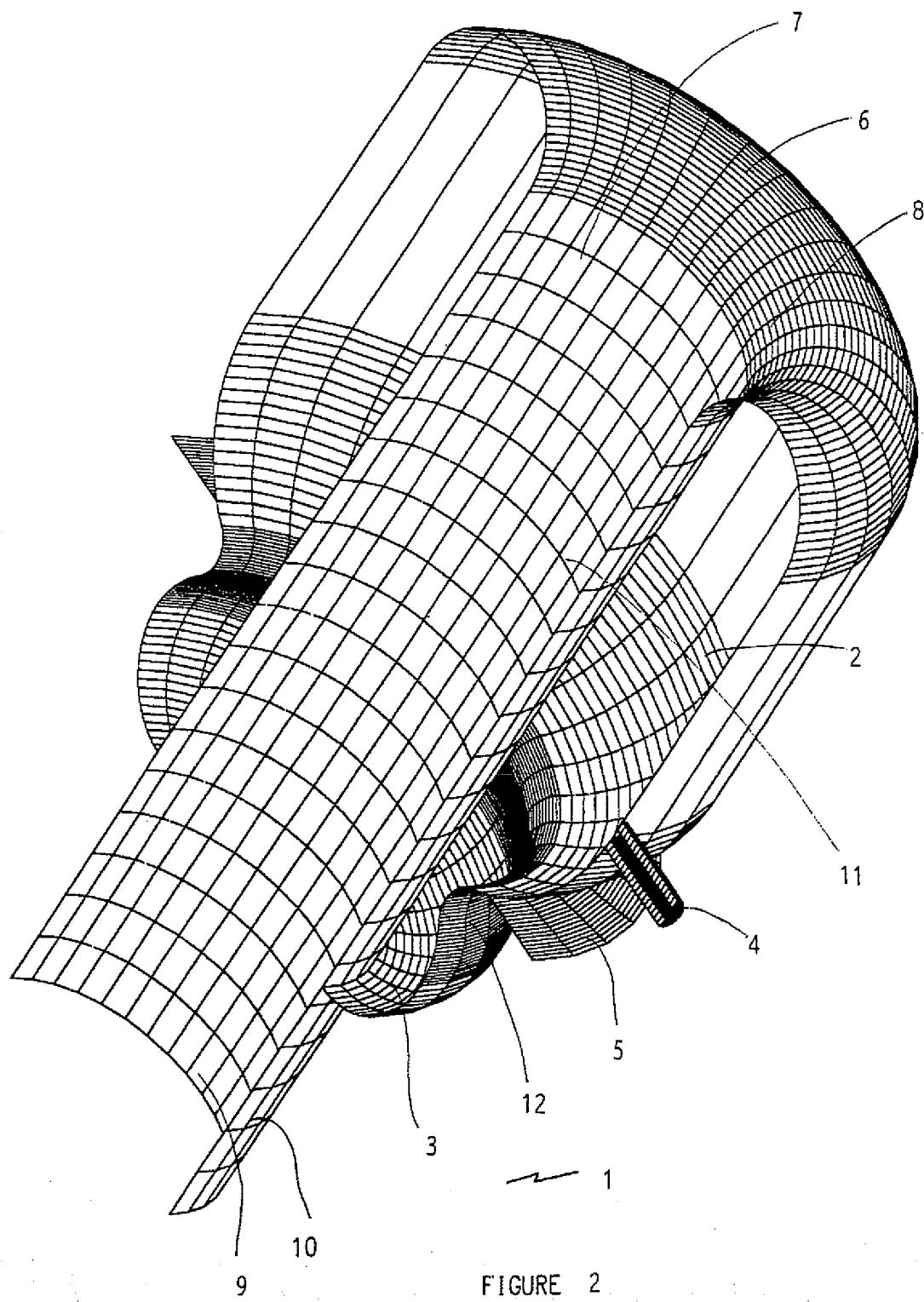


FIGURE 2

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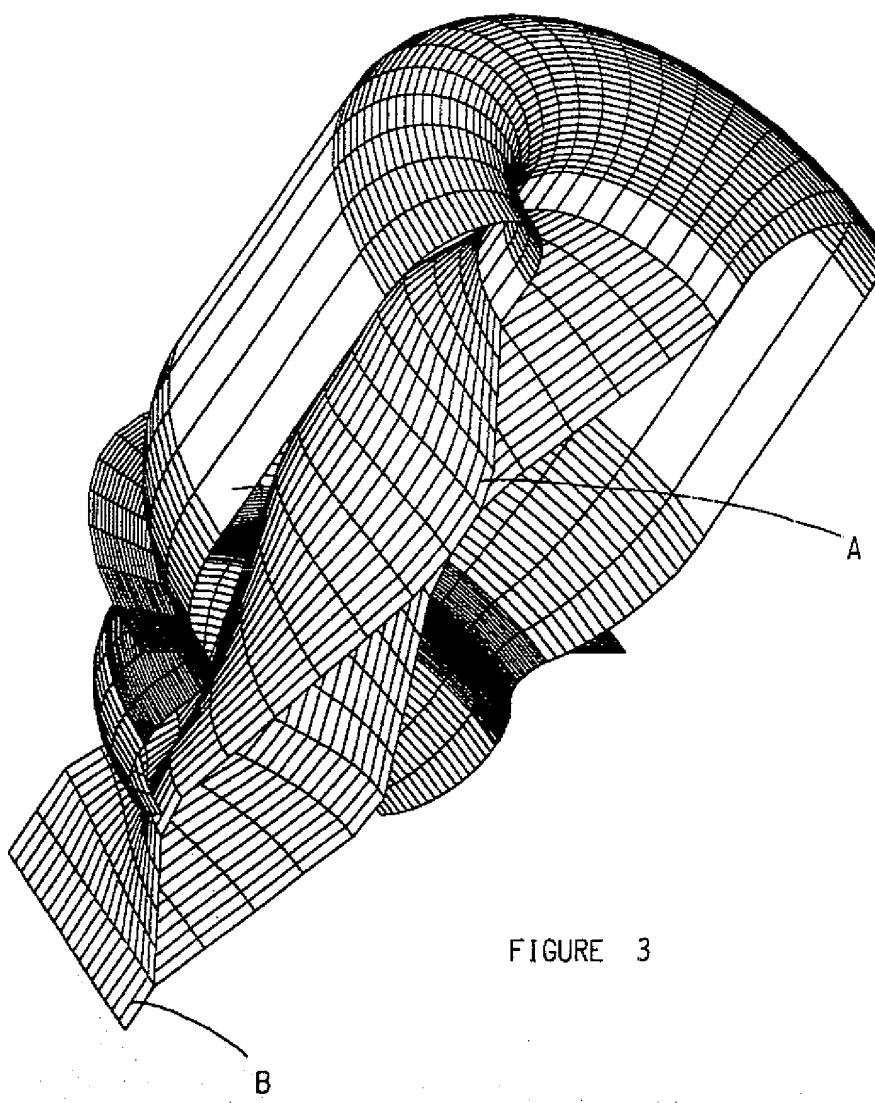


FIGURE 3

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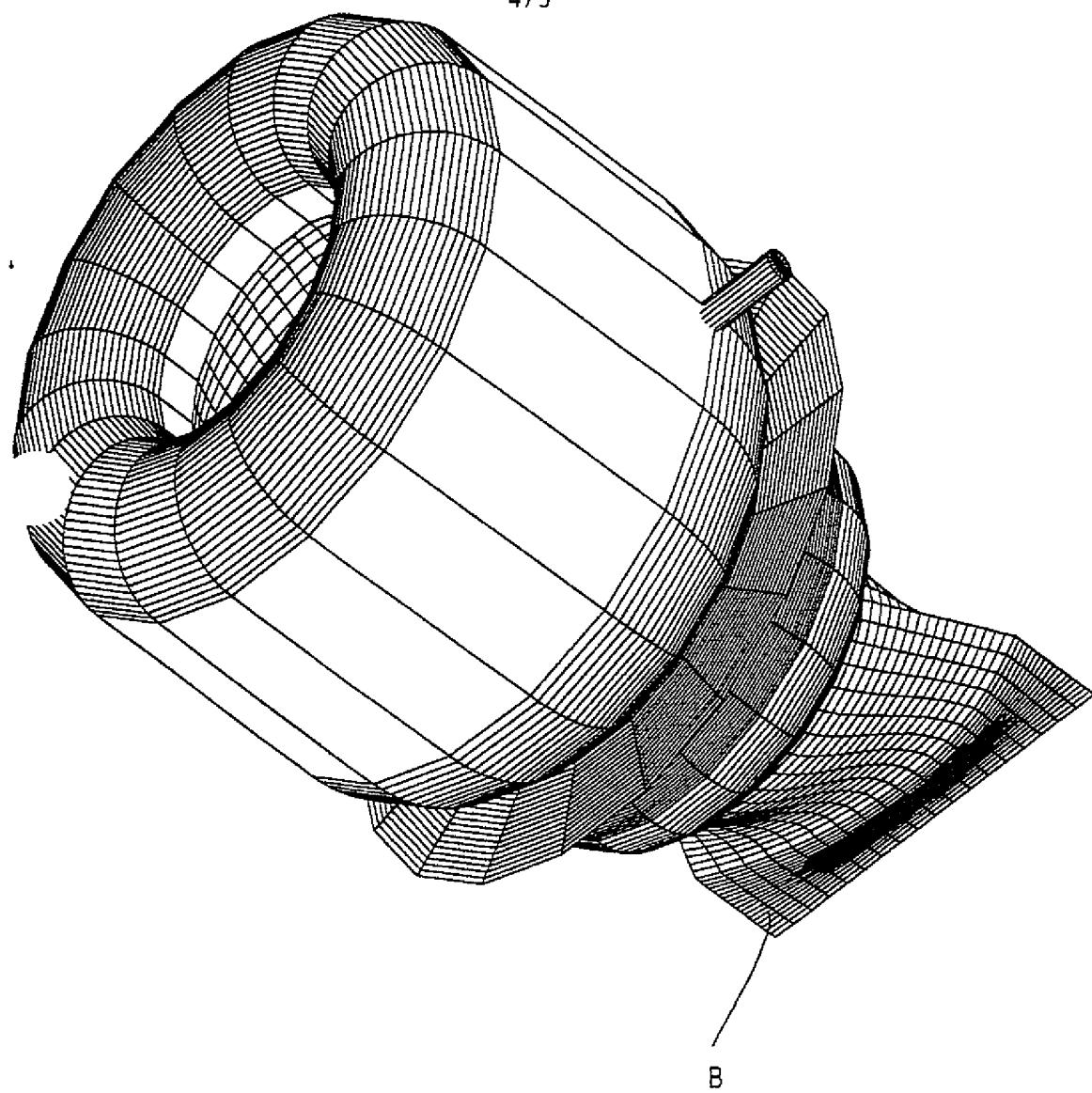


FIGURE 4

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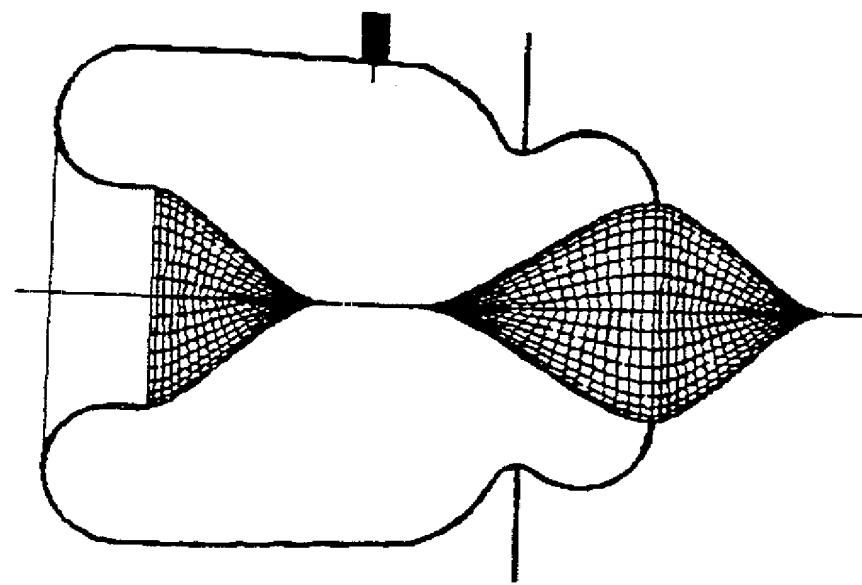


FIGURE 6

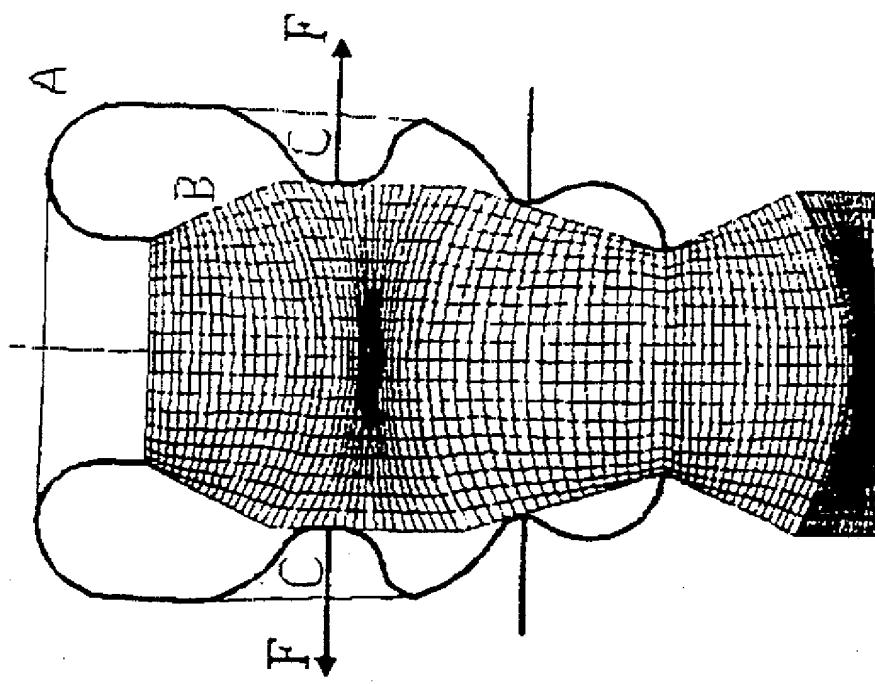


FIGURE 5